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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/727,006	11/30/2000	Victor L. Vines M.D.	108747.00004	3430

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EXAMINER
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SUN, XIUQIN

ART UNIT	PAPER NUMBER
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2863

DATE MAILED: 02/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/727,006

Applicant(s)

VINES M.D., VICTOR L.

Examiner

Xiugin Sun

Art Unit

2863

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 16-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 19-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of inventions I and II claims 1-15 and 19-21 (claims 7-15 was originally in group II, however, in amendment dated Nov. 13, 2002, these claims were amended to be a species of amended of claim 1) in Paper No. 5 is acknowledged.

Claims 7-15 are rejoined. Claims 16-18 stand withdrawn in view of the election without traverse of paper No. 5.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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3. Claims 7-9 and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Dimitriu et al. (U.S. Pat. No. 5396703).

Dimitriu et al. disclose an obstetrical vacuum extractor cup with force measuring capabilities, and teach a method of using a recording device to record a pressure in a vacuum device, the vacuum device enabled to couple to a fetus (col. 2, lines 11-220 and lines 40-51), comprising: placing the vacuum device on a fetus, the space between the fetus and the vacuum device having a pressure (col. 4, lines 51-67); initiating a vacuum pressure in the suction device (col. 4, lines 51-67 and col. 5, lines 29-40); detecting the vacuum pressure in the suction device (col. 5, lines 1-10, lines 29-40 and lines 55-65); and automatically recording the vacuum pressure in the suction device (col. 6, lines 26-37). The system taught by Dimitriu et al. further comprises: the step of engaging a monitor (col. 6, lines 26-37); the act of processing the recorded pressure to determine if the vacuum pressure is greater than a predetermined pressure (col. 5, lines 55-65); and the step of removing the suction device from the fetus (col. 5, lines 22-28).

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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5. Claims 1-4 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Watabe et al. (abstract and machine translation) in view of Dimitriu et al. (U.S. Pat. No. 5396703).

Watabe et al. teach a method for recording a pressure in a vacuum device which comprises the steps of: detecting a pressure in the vacuum device; recording the pressure in the vacuum device; and storing a record of the pressure (see section of abstract entitled 'Constitution' for explanation). Watabe et al. also teach storing that is achieved mechanically (the device is mechanically coupled to the recorder -see section 0021 of the machine translation). Watabe further teaches storing that is achieved electronically (the data is electrically stored to both hard and floppy disks through a personal computer-see section 0021 of the machine translation). Watabe et al. further teach the steps of coupling the recording device to the vacuum device and recording the pressure so that a record may be produced therefrom (see Drawing I and sections 0021-0023 of the machine translation). Watabe et al. further teach the step of generating, a warning signal (alarm) (See sections 0041 and 0042 of the machine translation).

Watabe et al. do not mention that: said vacuum device is enabled to couple to a fetus; said method further comprising the act of generating a warning signal when a predetermined pressure level is detected.

Dimitriu et al. disclose an obstetrical vacuum extractor cup with force measuring capabilities, wherein the vacuum extractor cup is enabled to couple to a fetus (col. 2, lines 18-22, lines 40-51; col. 3, lines 66-67; col. 4, lines 1-9 and lines 51-67).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to include the teaching of Dimitriu vacuum extractor cup in the Watabe system in order to apply the Watabe apparatus to facilitate the delivery of a child during childbirth (Dimitriu, col.1, lines 6-9).

The Watabe abstract discloses that "the use of the vacuum is discriminated as 'good' when the vacuum pressure is lower than a preset value after a prescribed period has elapsed or as 'not good' when the pressure is higher than the preset value. " It is unclear from the two references whether the alarm taught in the machine translation corresponds to the judgment of "not good" that is taught in the abstract of the disclosure (although it appears quite likely that they do correspond to one another).

However, at the time of the invention it would have been obvious to one having ordinary skill in the art at the time the invention was made to generate the warning signal when the "use of the vacuum" is discriminated as not good. The suggestion/motivation for doing so would have been to provide an easy means for notifying a user of a leak in the vacuum chamber (the vacuum chamber is "not good"). Therefore, it would have been obvious to modify the Watabe reference to obtain the invention as specified in claim 4.

6. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Watabe in view of Dimitriu et al. as applied to claim 1 above, and further in view of Kouketsu (U.S. Pat. No. 6289737 B1).

Watabe et al. and Dimitriu et al. do not explicitly teach the step of altering the pressure.

Kouketsu teaches the step of altering the pressure to achieve a second pressure (col. 3, lines 33-62).

At the time of the invention it would have been obvious to one having ordinary skill in the art to add the step of altering the pressure to the method of Watabe and Dimitriu. The suggestion/motivation for doing so would have been to provide improved control for the operation of the vacuum device (Kouketsu, col. 3, lines 33-62). Therefore, it would have been obvious to combine the Kouketsu reference with Watabe and Dimitriu in order to obtain the invention as specified in claim 5.

7. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Watabe in view of Dimitriu et al. as applied to claim 1 above, and further in view of Oda et al. (U.S. Pat. No. 6299691 B1).

Watabe et al. and Dimitriu et al. do not explicitly mention the step of releasing the pressure.

Oda et al. disclose the step of releasing the pressure (Fig. 7, step S20 and col. 1, lines 28-53).

At the time of the invention it would have been obvious to one having ordinary skill in the art to add step of releasing the pressure to the method of Watabe and Dimitriu. The suggestion/motivation for doing so would be so that the vacuum device could be safely opened (Oda, col. 1, lines 48-53). Therefore, it would have been

obvious to Combine the Oda et al. reference with Watabe and Dimitriu to obtain the invention as specified in claim 6.

8. Claims 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dimitriu et al. in view of Kouketsu (U.S. Pat. No. 6289737 B1).

Dimitriu et al. do not explicitly mention: the step of directing a change in the vacuum pressure, wherein the change is an increase in the vacuum pressure to move the vacuum pressure closer to atmospheric pressure, and wherein the change is a release of the vacuum pressure in order to achieve an atmospheric pressure; the step of altering the vacuum pressure in response to a direction to change the vacuum pressure; and the step of disengaging the vacuum pressure to achieve a local atmospheric pressure.

Kouketsu teaches the step of directing a change in the vacuum pressure, wherein the change is an increase in the vacuum pressure to move the vacuum pressure closer to atmospheric pressure, and wherein the change is a release of the vacuum pressure in order to achieve an atmospheric pressure; and the step of altering the vacuum pressure in response to a direction to change the vacuum pressure; and the step of disengaging the vacuum pressure to achieve a local atmospheric pressure (col. 3, lines 33-62; col. 8, lines 54-65 and col. 10, lines 11-20).

At the time of the invention it would have been obvious to one having ordinary skill in the art to add the steps of directing a change in the vacuum pressure and altering the vacuum pressure to the method of Watabe and Dimitriu. The suggestion/motivation



for doing so would have been to provide improved control for the operation of the vacuum device (Kouketsu, col. 3, lines 33-62). Therefore, it would have been obvious to combine the Kouketsu reference with Watabe and Dimitriu in order to obtain the invention as specified in claims 10-14.

9. Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Watabe in view of Dimitriu et al. as applied to claim 19 above, and further in view of Glenn A. Hunt, Master ASE Technician ([www.mityvac.com](http://www.mityvac.com)), [on-line], [retrieved on 1-13-2003].

Watabe et al. and Dimitriu et al. do not mention explicitly a vacuum device that comprises a MITYVAC or a disposable MITYVAC.

Hunt discloses MITYVAC pumps that can be used to create a vacuum.

At the time of the invention it would have been obvious to one having ordinary skill in the art to add a MITYVAC pump as taught by Hunt to the system of Watabe and Dimitriu. The suggestion/motivation for doing so would have been to achieve a near perfect vacuum in the vacuum chamber. Therefore, it would have been obvious to combine the Hunt's reference with Watabe and Dimitriu to obtain the invention as specified in claims 21 and 22.

### ***Response to Arguments***

10. Applicant's arguments with respect to claims 1-15 and 19-21 have been considered but are moot in view of the new ground(s) of rejection.

Claims 1-15 and 19-21 are rejected as new art (U.S. Pat. No. 6361542 B1) has been found to teach a system for monitoring a vacuum maintained in the fetal-coupled devices. Discussions are as set forth above.

### ***Conclusion***

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

### ***Contact Information***

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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Xiuqin Sun whose telephone number is (703)305-3467. The examiner can normally be reached on 7:00am-4:30pm.

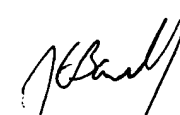
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Barlow can be reached on (703)308-3126. The fax phone numbers for the organization where this application or proceeding is assigned are (703)872-9318 for regular communications and (703)872-9319 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0956.



XS

January 13, 2003



John Barlow  
Supervisory Patent Examiner  
Technology Center 2800